

K083613

Title: 510(k) SUMMARY
Quanta System Polysurge Diode Laser Family

DEC 23 2000

Submitter: Quanta System SpA
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Date Prepared: June 16, 2008

Device Trade Name: Quanta System Polysurge Diode Laser Family

Common Name: Laser surgical instrument for use in general surgery and dermatology

Classification Name: Instrument, surgical, powered, laser

Predicate Devices:

- Quanta System Diode Medical Laser Family (K072034);
- INTERmedic Diode Laser Family (K053540);
- Dornier Medilase D Family Laser (K070536);
- Biolitec 150W Ceralas D 980nm Diode Laser (K072106);
- Trimedyne Optilase PL100 Nd:YAG Laser (K932883);
- CoolTouch LC215 Nd:YAG Laser (K072424);
- Biolitec 15W Ceralas D 1470nm Diode (K073063).
- Biolitec 50W Ceralas D 1950nm Diode (K072682).

Intended Use / Indications for Use: / The Quanta System Polysurge Diode Laser Family, including the Polysurge808, Polysurge940, Polysurge980, Polysurge1064, Polysurge1320, Polysurge1470 and Polysurge1950 (and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology),

Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.

LASER 808nm and 980nm

Urology:

- Lesions of external genitalia
- Circumcision
- Condyloma
- Bladder tumors
- Bladder neck incisions
- Vaporization of the prostate

General Surgery:

- Rectal and anal hemorrhoidectomy
- Mastectomy
- Dermabrasion
- Appendectomy (open and laparoscopic)
- Bowel resection (open and laparoscopic)
- Colectomy
- Liver resection
- Resection of organs
- Thyroidectomy
- Adhesiolysis
- Hepatobiliary tumors
- Thoracotomy
- Cholecystectomy (open and laparoscopic)
- Condyloma
- Breast biopsy

Neurosurgery:

- Percutaneous Disc Decompression (PLDD)
- Discectomy
- Hemostasis in conjunction with meningiomas

Gynecology:

- Cervical conization
- Myomectomy
- Endometrial ablation
- Ovarian cystectomy
- Appendectomy

Ophthalmology:

- Dacryocystorhinostomy
transcanalicular
- Open DCR
- Tumor excision
- Blepharoplasty

Orthopedics:

- Dissect and coagulate

Gastroenterology:

- Hemostasis of colonoscopy
- Hemostasis of esophageal varices
- Excision of polyps

Arthroscopy:

- Chondromalacia
- Synovectomy
- Meniscectomy

Thoracic Surgery:

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

Pulmonology:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary obstruction

Otolaryngology ENT:

- Removal of benign lesions from the ear, nose and throat
- Excision of carcinoma of the larynx
- Incision and excision of carcinoma in situ
- Neck dissection
- Laryngeal papillomectomy
- Removal of vocal cord/fold nodules, polyps and cyst

Dental Application:

- Frenectomy
- Frenotomy
- Biopsy

- Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

Pulmonary Surgery:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary or stricture

Cardiac Surgery:

- Coagulation and hemostasis of cardiac tissue

Dermatology/Aesthetics:

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminata, warts, small non malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridment.
- Seborrhic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

Plastic Surgery:

- Cut, coagulation & vaporization
- Resurfacing non
- Blepharoplasty

Vascular Surgery:

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

LASER 940nm:

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Radiology.

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, and for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85 cc.

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including marginal and inter-dental gingival and epithelial lining of free gingival and the following specific indications: Excisional and incisional biopsies Exposure of unerupted teeth; Fibroma removal; Frenectomy; Frenotomy; Gingival troughing for crown impressions;

Gingivectomy; Gingivoplasty; Gingival incision and excision; Haemostasis and coagulation; Implant recovery; Incision and drainage of abscess; Leukoplakia; Operculectomy; Oral papillectomies; Pulpotomy; Pulpotomy as an adjunct to root canal therapy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa; Vestibuloplasty

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for Laser Periodontal procedures, including: Laser soft tissue curettage; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

LASER 980nm:

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein.

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology)

Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in

the oral cavity. Examples include:

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in

- situ
- Ablation and vaporization of hyperkeratosis
- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

Arthroscopy

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint

tissues during arthroscopic surgery. Examples include:

- Meniscectomy
- Synovectomy
- Chondromalacia

Gastroenterology

Hemostasis, incision, excision, ablation, coagulation and vaporization of

tissue in the upper and lower gastrointestinal tracts and also with

endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

General Surgery, Dermatology, Plastic Surgery and Podiatry

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion.

Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions

- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and hemostasis of capillary hemangioma
- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Photocoagulation of teleangectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.
- Treatment of reticular veins and branch varicosities

Urology

Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues. Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia
- Vaporization of the prostate to treat benign prostatic hyperplasia (BPH)

Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial

- neoplasia
- Cervical conization
- Menorrhagia

Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Examples include: hemostasis in conjunction with meningiomas

Cardiac Surgery

Hemostasis and coagulation of soft tissue, including cardiac tissue.

Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

Dental Applications

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux

Indicated for use with the ELVes Procedure Kit in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

LASER 1064nm

DERMATOLOGY/ PLASTIC SURGERY

Photocoagulation:

- Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful)

DISCECTOMY

Percutaneous Lumbar Discectomy

GASTROINTESTINAL

Tissue Ablation:

- Benign and Malignant Neoplasm
- Polyps
- Colitis
- Ulcers
- Aniodysplasia
- Hemorrhoids

Hemostasis:

- Varices
- Esophangitis
- Esophageal Ulcer
- Mallory-Weiss Tear
- Gastric Ulcers
- Duodenal Ulcers
- Non-bleeding Ulcers
- Gastric Erosions

GENERAL SURGERY

Soft Tissue:

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation

Vessel Coagulation

GENITOURINARY SURGERY

Ablation and Hemostasis:

- Superficial Urinary Bladder Tumors
- Invasive Bladder Carcinoma
- Urethral Strictures
- Lesions of the External Genitalia

GYNECOLOGICAL TISSUE ABLATION

- Endometrial Ablation (menorrhagia)
- Soft Tissue Excisional Conization
- Submucous Fibroids
- Polyps
- Septa

NEUROSURGERY

Hemostasis

ORTHOPEDIC SURGERY

Soft Tissue (incision and excision):

- Knee
- Shoulder

OTORHINOLARYNGOLOGY SURGERY

Soft Tissue:

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation

- Vessel Coagulation

PROSTATECTOMY

Soft Tissue Coagulation:

- Benign Prostatic Hyperplasia (BPH Prostatectomy)

PULMONARY SURGERY

Palliative Treatment:

- Benign and Malignant Pulmonary Airway Obstructions

LASER 1320 nm

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles. For treatment of back acne and atrophic acne scars. For treatment of reflux of the great and small saphenous veins associated with varicose veins and varicosities.

LASER 1470nm:

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for delivery of laser light to soft tissue in non-contact mode during general surgery procedures. The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

LASER 1950nm:

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral strictures
- Bladder neck incisions

- Ablation and resection of bladder tumors, urethral tumors and ureteral tumors
- Ablation of Benign Prostatic hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate (HoLRP)
- Laser Enucleation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of the external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non-bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric erosions

Thoracic/Pulmonary Surgery

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Laryngeal lesions
- Airway obstruction including carcinoma
- Polyps and granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Intra-uterine treatment of submucous fibroids, benign
- endometrial polyps and uterine septum by incision, excision,
- ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of
- the cervix
-

Ear, Nose and Throat (Otolaryngology)

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Endonasal/sinus surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and
- laryngeal
- Tonsillectomy
- Adenoidectomy

Dermatology/Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue in therapeutic plastic, dermatologic

and aesthetic procedures including:

- Basal Cell carcinomas
- Lesions of the skin and subcutaneous tissue
- Skin tags
- Plantar warts

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

Ablation of soft and cartilaginous tissue in minimally invasive spinal surgery including:

- Percutaneous laser disc decompression/discectomy (PLDD)
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesions
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of decubitus ulcers
- Hemorrhoids
- Debridement of statis ulcers

**Technological
Characteristics:**

- Biopsy

The Polysurge Diode Laser System includes seven models :

Models	Wavelength	Laser Power
Polysurge808	808nm	50, 90W
Polysurge940	940nm	50, 120W
Polysurge980	980nm	50, 100, 150W
Polysurge1064	1064nm	50, 100W
Polysurge1320	1320nm	10W
Polysurge1470	1470nm	15W
Polysurge1950	1950nm	50W

- Model **Polysurge808** is indicated for Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy (PLDD), Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.
- Model **Polysurge940** is indicated for Urology (BPH), Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Radiology, Endovascular Surgery and Dental Procedures.
- Model **Polysurge980** is indicated for use in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology (BPH), gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein

- Model **Polysurge1064** is indicated for use in **Endoscopic / Laparoscopic General Surgery, Gastroenterology, General Surgery, Gynecology, Head and Neck / Otorhinolaryngology (ENT), Neurosurgery, Oculoplastics, Orthopedics, Plastic Surgery, Pulmonary Surgery, Thoracic Surgery, Urology.**
- Model **Polysurge1320** is indicated for use in **Dermatology and endovascular surgery.**
- Model **Polysurge1470** is indicated for use in **endovascular surgery.**
- Model **Polysurge1950** is indicated for use in **Urology, Gastroenterology, Thoracic/Pulmonary Surgery, Gynecology, Ear, Nose and Throat (Otolaryngology), Dermatology/Plastic Surgery, Arthroscopy, General Surgery**

The Polysurge Diode Laser Family is designed with 5 major subsystems: (1) an external structure; (2) power electronics; (3) display with control electronics; (4) the laser system with an opto-mechanical block and (5) the cooling system. In addition to the five subsystems, the Polysurge Diode Laser Family incorporates several safety features, including a remote interlock, an emergency red push button and a key switch.

The external structure is composed of a polyurethane shell with a frontal panel containing the touch screen display, the optical fiber connection (SMA 905) and the calibration port. On this panel the key switch and the operation led are inserted too. On the rear panel the footswitch connectors, the remote interlock, the power switch, the RS232 interface connector are located . The emergency red push button is located on the upper part of the box.

The power electrical system is composed of a three power supply. The control electronic, based on a microcontroller, manage the power electronic, the current control, the thermalization of the laser source and control the user interface

The laser system is composed of an opto-mechanical block containing the laser source, the diode laser dissipation system (a Peltier's element and cooling system with distilled water), the fiber launching system, the red diode aiming beam, and the power calibration system.

The cooling system is composed of a water pump, a flow

Performance Data

switch, a heat exchanger, deionizing cartridge and water filter.

**Substantial
Equivalence:**

The external accessories include separate optical fibers and hand pieces for dental, dermatological and surgical applications, or for endovascular applications.

None

The Quanta System Polysurge Diode Laser Family is as safe and effective as the predicate devices. The Polysurge Diode Laser Family has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Polysurge Diode Laser Family and its predicate devices raise no new issues of safety or effectiveness. Thus, the Polysurge Diode Laser Family is substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

Quanta System, S.P.A.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

Re: K083613

Trade/Device Name: Polysurge Diode Laser Family

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and
in dermatology

Regulatory Class: II

Product Code: GEX

Dated: December 5, 2008

Received: December 8, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 083613

Device Name: **Polysurge Diode Laser Family**

Indications for Use:

The Quanta System Polysurge Diode Laser Family, including the Polysurge808, Polysurge940, Polysurge980, Polysurge1064, Polysurge1320, Polysurge1470 and Polysurge 1950 (and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.

LASER 808nm and 980nm

Urology:

- Lesions of external genitalia
- Circumcision
- Condyloma
- Bladder tumors
- Bladder neck incisions
- Vaporization of the prostate

General Surgery:

- Rectal and anal hemorrhoidectomy
- Mastectomy
- Dermabrasion
- Appendectomy (open and laparoscopic)
- Bowel resection (open and laparoscopic)
- Colectomy
- Liver resection
- Resection of organs
- Thyroidectomy
- Adhesiolysis
- Hepatobiliary tumors
- Thoracotomy
- Cholecystectomy (open and laparoscopic)
- Condyloma
- Breast biopsy

Neurosurgery:

- Percutaneous Disc Decompression (PLDD)

- Dissectomy
- Hemostasis in conjunction with meningiomas

Gynecology:

- Cervical conization
- Myomectomy
- Endometrial ablation
- Ovarian cystectomy
- Appendectomy

Ophthalmology:

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor excision
- Blepharoplasty

Orthopedics:

- Dissect and coagulate

Gastroenterology:

- Hemostasis of colonoscopy
- Hemostasis of esophageal varices
- Excision of polyps

Arthroscopy:

- Chondromalacia
- Synovectomy
- Meniscectomy

Thoracic Surgery:

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

Pulmonology:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary obstruction

Otolaryngology ENT:

- Removal of benign lesions from the ear, nose and throat
- Excision of carcinoma of the larynx
- Incision and excision of carcinoma in situ
- Neck dissection
- Laryngeal papillomectomy
- Removal of vocal cord/fold nodules, polyps and cyst

Dental Application:

- Frenectomy
- Frenotomy
- Biopsy
- Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

Pulmonary Surgery:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary or stricture

Cardiac Surgery:

- Coagulation and hemostasis of cardiac tissue

Dermatology/Aesthetics:

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminata, warts, small non malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridment.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

Plastic Surgery:

- Cut, coagulation & vaporization
- Resurfacing non
- Blepharoplasty

Vascular Surgery:

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

LASER 940nm:

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Radiology.

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, and for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85 cc.

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including marginal and inter-dental gingival and epithelial lining of free gingival and the following specific indications: Excisional and incisional biopsies Exposure of unerupted teeth; Fibroma removal; Frenectomy; Frenotomy; Gingival troughing for crown impressions; Gingivectomy; Gingivoplasty; Gingival incision and excision; Haemostasis and coagulation; Implant recovery; Incision and drainage of abscess; Leukoplakia; Operculectomy; Oral papillectomies; Pulpotomy; Pulpotomy as an adjunct to root canal therapy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa; Vestibuloplasty

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for Laser Periodontal procedures, including: Laser soft tissue curettage; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

LASER 980nm:

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous

system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein.

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology)

Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include:

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in situ
- Ablation and vaporization of hyperkeratosis
- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

Arthroscopy

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:

- Meniscectomy
- Synovectomy
- Chondromalacia

Gastroenterology

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

General Surgery, Dermatology, Plastic Surgery and Podiatry

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion.

Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions

- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and hemostasis of capillary hemangioma
- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Hernioraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Photocoagulation of teleangiectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.
- Treatment of reticular veins and branch varicosities

Urology

Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues. Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia
- Vaporization of the prostate to treat benign prostatic hyperplasia (BPH)

Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Examples include: hemostasis in conjunction with meningiomas

Cardiac Surgery

Hemostasis and coagulation of soft tissue, including cardiac tissue.

Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

Dental Applications

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux

Indicated for use with the ELVes Procedure Kit in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

LASER 1064nm

DERMATOLOGY/ PLASTIC SURGERY

Photocoagulation:

- Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful)

DISCECTOMY

Percutaneous Lumbar Discectomy

GASTROINTESTINAL

Tissue Ablation:

- Benign and Malignant Neoplasm
- Polyps
- Colitis
- Ulcers
- Aniodysplasia
- Hemorrhoids

Hemostasis:

- Varices
- Esophangitis
- Esophageal Ulcer
- Mallory-Weiss Tear
- Gastric Ulcers
- Duodenal Ulcers
- Non-bleeding Ulcers
- Gastric Erosions

GENERAL SURGERY

Soft Tissue:

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation

Vessel Coagulation

GENITOURINARY SURGERY

Ablation and Hemostasis:

- Superficial Urinary Bladder Tumors
- Invasive Bladder Carcinoma
- Urethral Strictures
- Lesions of the External Genitalia

GYNECOLOGICAL TISSUE ABLATION

- Endometrial Ablation (menorrhagia)
- Soft Tissue Excisional Conization
- Submucous Fibroids
- Polyps
- Septa

NEUROSURGERY

Hemostasis

ORTHOPEDIC SURGERY

Soft Tissue (incision and excision):

- Knee
- Shoulder

OTORHINOLARYNGOLOGY SURGERY

Soft Tissue:

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation
- Vessel Coagulation

PROSTATECTOMY

Soft Tissue Coagulation:

- Benign Prostatic Hyperplasia (BPH Prostatectomy)

PULMONARY SURGERY

Palliative Treatment:

- Benign and Malignant Pulmonary Airway Obstructions

LASER 1320 nm

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles. For treatment of back acne and atrophic acne scars. For treatment of reflux of the great and small saphenous veins associated with varicose veins and varicosities.

LASER 1470nm:

The Quanta System Polysurge Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for delivery of laser light to soft tissue in non-contact mode during general surgery procedures. The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

LASER 1950nm:

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral strictures
- Bladder neck incisions
- Ablation and resection of bladder tumors, urethral tumors and ureteral tumors
- Ablation of Benign Prostatic hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate (HoLRP)
- Laser Enucleation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of the external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non-bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular malformation

- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric erosions

Thoracic/Pulmonary Surgery

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Laryngeal lesions
- Airway obstruction including carcinoma
- Polyps and granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Intra-uterine treatment of submucous fibroids, benign
- endometrial polyps and uterine septum by incision, excision, ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

Ear, Nose and Throat (Otolaryngology)

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Endonasal/sinus surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

Dermatology/Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue in therapeutic plastic, dermatologic and aesthetic procedures including:

- Basal Cell carcinomas
- Lesions of the skin and subcutaneous tissue
- Skin tags
- Plantar warts

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

Ablation of soft and cartilaginous tissue in minimally invasive spinal surgery including:

- Percutaneous laser disc decompression/discectomy (PLDD)
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesions
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of decubitus ulcers
- Hemorrhoids
- Debridement of statis ulcers

- Biopsy

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) _____



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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